

REMARKS

Applicants request reconsideration and withdrawal of the outstanding rejection based on the foregoing amendments and following remarks. Claim 32 has been amended and claims 34-36 and 42-46 have been cancelled. No new matter has been added.

Response to Rejections under 35 U.S.C. § 112

Claims 34 and 35 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner asserts that claim 34 is unclear because it is not clear whether blood sugar is determined in fasting individuals or certain values in fasting individuals are picked up and reported. With regard to claim 35, the Examiner asserts that "associated forms and/or performs" is unclear. We propose correcting the typographical error in claim 35, i.e., amending 'performs' to recite 'preforms' and referring the examiner to the definition of these terms in the specification on page 6, lines 31-36, which discloses that these forms and/or preforms include "the secondary diabetes forms, potential diabetes, latent diabetes, decreased glucose tolerance and/or clinically manifest diabetes." Without acceding to the proprieties of the Office Action rejections and only in the interest of advancing prosecution, Applicants submit that claims 34 and 35 have been cancelled, thereby rendering the rejection moot. Applicants respectfully request that the rejection be withdrawn.

Response to Rejections under 35 U.S.C. § 102

Claims 32-46 remained rejected under 35 U.S.C. § 102(b) as being anticipated by Tölle (WO/2001/010245- English equivalent: U.S. 6,706,294). The Examiner maintained that Tölle disclosed every element of the claimed method based on inherency. With regard to Applicants' previous argument that Tölle found a process for preparing food, dietetic foods and food additives based on distillers' grains which no longer exhibit disturbing flavors, the Examiner asserts that Tölle discloses the determination of an effective dose for treatment and mentions the words "actives," therefore the product must have some kind of nutritional/medicinal use. Applicants respectfully disagree with and traverse the Examiner's characterization of Tölle because:

- 1) there is no mention of the word "effective" in Tölle and
- 2) the doses that the Examiner refers to as allegedly being "effective" were not determined based on nutritional or medical research regarding efficacy, but rather,
- 3) the doses determined in Tölle are based on research to degrade "disturbing flavor" to prepare a formulation that yields "tasty selling units."

Thus, Applicants submit that the Examiner's arguments appear to read more into Tölle than Tölle disclosed or even contemplated.

However, in the interest of advancing prosecution and without acceding to the proprieties of the Office Action rejections, independent claim 32 has been amended to require the steps of a) determining whether a patient is in a fasting or postprandial condition; b) in case the patient is in a fasting condition, determining said patient's fasting blood sugar value, and if said patient's fasting blood sugar value is ≥ 110 mg/dl,

administering to said patient a composition comprising distillers grains which have been fermented with yeast and also have been fermented with a yogurt culture and/or a butter culture in an amount effective to lower said patient's increased blood sugar value;

c) in case the patient is in a postprandial condition, determining said patient's postprandial blood sugar value and, if said patient's postprandial blood sugar value is \geq 140 mg/dl, administering to said patient a composition comprising distillers grains which have been fermented with yeast and also have been fermented with a yogurt culture and/or a butter culture in an amount effective to lower said patient's increased blood sugar value. Written description support for the amendment can be found, *inter alia*, in the paragraph bridging pages 3 and 4 and on page 4, lines 26-39 of the specification. No new matter has been added.

Applicants submit that 'fasting blood sugar value' is a well established technical term in connection with diabetes. For example, in Wikipedia, a copy of the respective website is enclosed herewith, it can be found that fasting blood glucose levels are measured after a fast of eight hours (see chapter "Clinical correlation"). Furthermore there even exists an established FBS test (fasting blood sugar) (see chapter "Blood glucose laboratory tests"). Further, according to WebMD FBS, fasting blood sugar values are derived from persons who have not eaten for at least 8 hours. Similarly, with "Lab Tests Online®" it can be found that if blood glucose is measured on a fasting basis, values are collected after 8 to 10 hours fast (see line 3). The same result can be derived from the website www.healthypinoy.com according to which the fasting blood sugar value is determined by taking a sample of venous blood after an overnight fasting. Copies of the aforementioned documents are submitted herewith.

Postprandial blood sugar values are defined in the specification as the respective blood sugar value taken two hours after meal (see page 4, lines 26-28 of the specification). This is also evident from the afore-mentioned document WebMD according to which "the 2-hour postprandial blood sugar measures blood glucose exactly two hours after you start eating a meal."

Applicants submit that Tölle does not disclose or suggest the steps of the presently claimed method and respectfully request that the rejections be withdrawn.

Furthermore, Applicants submit that Tölle exclusively relates to double fermented grain as a food supplement containing fiber. Tölle does not provide a link between the administration of double fermented grain and treating diabetics as has been asserted, and does not hint at treating increased blood sugar in a patient. Therefore, Tölle does not disclose or suggest the steps of the presently claimed method. Tölle only discloses that double fermented grain, which is healthy for everybody including diabetics, is suited for diabetics due to the low amount of sugars and carbohydrates in the composition. The same conclusion can be derived from column 2, line 45, of Tölle where reference is made to additives such as milk preparations with sweetening agents or fructose. Clearly, Tölle teaches that if double fermented grain is used with milk, care should be taken to not add regular sugar but rather sweetening agents or fructose. This passage clearly highlights that Tölle is far from disclosing or suggesting that by use of double fermented grain the blood sugar value **can be lowered**. Instead Tölle is merely providing a substitute food to reduce the amount of sugar consumed. Accordingly, while Tölle discloses a number of diseases that may be treated by administering double fermented grain, the list of diseases does not mention diabetes (column 2, lines 55 to

61). In view of the many references to diabetics in Tölle, this omission indicates that Tölle did not foresee treatment of diabetics.

Moreover, Applicants submit that Tölle does not disclose or suggest significant improvements in terms of a reduction of fasting insulin level, HOMA-IR and blood sugar can be achieved even after elimination of the interfering factor "weight," as demonstrated in the examples of the present application. The inventor's have demonstrated the unexpected and surprising results that are achieved according to the presently claimed method, which is effective in treating a patient suffering from increased blood sugar value beyond merely effecting a weight decrease. See, e.g., pages 8-10 of the instant specification. The present application discloses that "[i]n this case, the absolute improvement of the HOMA-Index was of interest, but of still more interest was the relative improvement of the HOMA-Index after cancellation of the effect caused by weight loss. In this way, it is possible to determine the effect solely caused specifically by the treatment." Page 17, lines 19-24 of the specification.

Further, the present specification states that "...it should be emphasized for the 'Vibamin®'-treated subjects that the improvement of the fasting blood sugar, the fasting insulin and the main parameter HOMA-Index, even after elimination of the interfering parameter "weight", remained significant ($p = 0.005$; $p = 0.03$ and $p = 0.007$), whereas in the comparison product, only the weight reduction caused the improvement." Page 18, lines 1-8.

Because Tölle does not disclose or suggest the steps of the presently claimed method, Applicants respectfully request that the rejection be withdrawn and the claims be passed to issue.

Conclusions

In view of the above amendments and remarks hereto, Applicants believe that all of the Examiner's rejections set forth in the August 27, 2010 Office Action have been fully overcome and that the present claims fully satisfy the patent statutes. Applicants, therefore, believe that the application is in condition for allowance.

The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

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Enclosures:

1. "Fasting Blood Sugar" by Dr. Joseph D. Tabora, www.healthpinoy.com
2. "Diabetes Health Center" WebMD, www.diabetes.webmd.com
3. "Blood Sugar" Wikipedia
4. "Glucose" Lab Tests Online, www.labtestsonline.org

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